

March 30th, 2005
SECTION II
510(k) SUMMARY

APR 24 2006

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

K052520

Submitter:

Tianjin New Bay Bioresearch Co., Ltd.
#3 Jian She Rd, Ba Li Tai Industry Area Jin Nan District,
Tianjin, China
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Facsimile: 86-222-875-1516

Contact Person:

Rodrigo Berlie
New Product Development Director
Telephone: (760) 602-2929
Facsimile: (760) 602-2999

Preparation Date:

May 30, 2005

Device Information:

Device Classification Name: Immunoassay, Amphetamine, Methamphetamine, Benzoyllecgonine, 11-nor- Δ -9-THC-9-COOH, Morphine, Phencyclidine.
Common/Usual Name: Immunoassay Test System for detection of Multiple Drug (up to 6) Screen Test Device in Human Urine
Proprietary Name: Rapid Forsure One Step Multiple Drug (up tp 6) Screen Test Device for Amphetamine, Methamphetamine, Benzoyllecgonine, THC, Morphine and Phencyclidine Test
Regulation Number: 21 CFR§862.3650
Regulatory Name: Amphetamine, Methamphetamine, Benzoyllecgonine, THC Morphine and Phencyclidine test system
Product Code: DJG ✓
Regulatory Class: Class II

Predicate Devices:

Rapid One Step Strip Buprenorphine Test is substantially equivalent to Monitect Multiple Drug Screen MOR2000/MET/THC/COC/PCP of Branan Medical Corporation, cleared by FDA(K004034), and GC/MS for its stated intended use.

Device Description:

New Bay For Sure One Step single and Multiple Drug Screen Test card consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows through the absorbent device, the Colloidal Gold labeled antibody- conjugate binds to the free drug in the specimen forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the Test reaction zone and will not produce a magenta color band when the drug is above the detection level of 1000 ng/ml of Amphetamine, 1000 ng/ml of Methamphetamine, 50 ng of THC, 2000ng/ml of Morphine, 300 ng of Benzoyllecognine 25 ng/ml of Phencyclidine. Unbound colloidal gold-labeled antibody conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A **NEGATIVE** specimen produces two distinct color bands in both the specific drug test region and control area. A **POSITIVE** specimen produces only one color band in the control area and no color band on the specific drug test region . There is no meaning attributed to color or its intensity for either line. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Intended Use:

The Forsure One step single and Multiple Drug screen Amphetamine, THC, Morphine, Methamphetamine, Benzoyllecognine and Phencyclidine Cassette Test are a Chromatographic immunoassay for qualitative determination of the presence of **Amphetamine** at a cutoff concentration of 1000 ng/ml, **Methamphetamine** at a cutoff concentration of 1000 ng/ml, **THC** at a cutoff concentration of 50 ng/ml, **Morphine** at a cutoff concentration of 2000 ng/ml, **Benzoyllecognine** at a cutoff concentration of 300 ng/ml , **Phencyclidine** at a cutoff concentration of 25 ng/ml. The assay provides a simple and rapid analytical screening procedure to detect Amphetamine, THC, Morphine, Methamphetamine, Benzoyllecognine and Phencyclidine in human urine. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Comparison to Predicate Device(s):

Forsure Multiple Rapid One Step Drug Screen Test is substantially equivalent to Branen's Monitect Drug Screen Cassette Test system cleared by FDA, e.g., the Brana's Monitect Assay (004034)and GC/MS for its stated intended use.

Device Characteristics	Subject Device	Predicate Device(s)
		Monitect Drug Screen Cassette Assay (K004034) and GC/MS
Intended Use	Forsure Multiple Drug Screen one step Immunochromatographic Qualitative test . The assay provides a simple and rapid analytical screening procedure to detect up to six different abuse drug (Amphetamine,Methamphetamine, Benzoylgonine, THC, Morphine,and Phencyclidine) in human urine	Monitect Multiple Drug Screen immunochromatographic assay for qualitative determination of the presence of up to five different drug (Amphetamine, Methamphetamine, THC, Benzoylgonine, Phencyclidine in human urine.
Analyte	Amp,Mamp,BEG,THC,MOR,PCP	AMP,Mamp,BEG,THC,PCP
Cutoff	Amp;1000 ng/ml, Mamp;1000 ng/ml, BEG :300 ng/ml, THC : 50 ng/ml. MOR; 2000 ng/ml. PCP :25 ng/ml.	Amp: 1000 ng/ml, Mamp;1000ng/ml BEG; 300 ng/ml THC ; 50 ng/ml PCP ; 25 ng/ml
Matrix	Urine	Urine
Calibrator	None	None
Instrument	None, Visual read single use	None, Visual Read single use
Calibration of Reagent	None	None
Storage	Below 28 °C until expiration	15°C - 30°C until expiration date

Summary:

The information provided in this pre-market notification demonstrates that Forsure Rapid One Step Multiple up to six Drug Screen Test Device is substantially equivalent to Branen's Monitect Drug Screen Cassette Test system and GC/MS. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supplied in this pre-market notification provides reasonable assurance that the Forsure Multiple Rapid One Step Drug Screen Test is safe and effective for its stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tianjin New Bay Bioresarch Co., Ltd.
c/o Mr. Rodrigo Berlie
New Product Development Director
Aventir Biotech, LLC.
3108 Avenida Olmeda
Carlsbad, CA 92009

APR 24 2006

Re: k052520

Trade/Device Name: Forsure One Step Multiple (Up to Six) Drug Screen Test Card for Amphetamine, Methamphetamine, Bezoylcegonine, 11-nor- Δ -9 Tetrahydrocannabinol-9-carboxylic acid, Morphine and Phencyclidine.

Regulation Number: 21 CFR§862.3100

Regulation Name: Amphetamine test system

Regulatory Class: Class II

Product Code: DKZ, DJC, DIO, DPK, LDJ, LCM

Dated: April 18, 2006

Received: April 19, 2006

Dear Mr. Berlie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

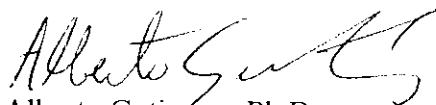
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 --

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez".

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k052520

Device Name:

Forsure One Step Multiple (Up to Six) Drug Screen Test Card for Amphetamine, Methamphetamine, Bezoylcegonine, 11-nor- Δ -9-Tetrahydrocannabinol-9-carboxylic acid, Morphine and Phencyclidine.

Indications for Use:

Forsure One Step Multiple (Up to Six) Drug Screen Test Card is a prescription assay intended for professional use in central laboratories only. It provides qualitative screening results for Amphetamine (AMP), Methamphetamine (MET), Bezoylcegonine (BEG/COC), 11-nor- Δ -9-Tetrahydrocannabinol-9-carboxylic acid (THC), Morphine (MOR/OPI) and Phencyclidine (PCP) in human urine at cut off concentrations of AMP 1000 ng/ml, MET 1000 ng/ml, BEG 300 ng/ml, THC 50ng/ml, MOR 2000 ng/ml and PCP 25ng/ml. The device may include as few as one and as many as six individual assays. For In Vitro Diagnostic Use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly in evaluating a preliminary positive. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

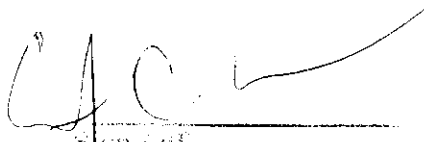
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
k052520